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EXAMINER	
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1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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CONTINUATION SHEET

With respect to the rejection of claims 9, 21 and 22 under 35 U.S.C. 112, first paragraph (new matter), Applicant's arguments filed 9/22/2009 have been fully considered but they are not persuasive.

The response notes that the CAFC in *In re Wright*, 9 USPQ2d 1649 (Fed. Cir. 1989) clearly held that the test for whether a recited feature is supported by the original disclosure is not whether there is an explicit recitation in the specification of the words used in the claims, but rather whether the feature would be clear to one skilled in the art when reading the claims, not just in view of the specification, but also in view of the known art at the time of the invention. *Id at 1651*. The court in Wright further reiterated that "the claimed subject matter need not be described in *haec verba* in the specification in order for that specification to satisfy the description requirement". *Id at 1650*.

This argument is not found persuasive. While there is no in *haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). In the instant case, the amendment to require the step of "measuring the efficacy of any chemical compound, which is identified as having the ability to block the ClC-7 chloride channel, in treating osteoporosis, osteolytic cancer invasion, or Paget's disease of bone" is not supported through express, implicit or inherent disclosure. The specification does not provide support for any method steps that would provide a measure of therapeutic efficacy, such

as administration of the compound to a cell culture model or animal model of osteoporosis, osteolytic cancer invasion or Paget's disease of bone. The method steps disclosed in the specification do not explicitly or inherently result in measurement of efficacy in treating these diseases. One skilled in the art would have recognized that the method steps disclosed in the present specification were directed to identifying compounds that have activity in blocking the ClC-7 channel (e.g., Maher et al. US Patent No. 6,686,193 B2, cited in a prior action, especially columns 46-48, the paragraph bridging columns 58-59, and Table 3). Upon reading the present specification, one of skill in the art would not have recognized that the added step of measuring the therapeutic efficacy to be a correction of an obvious error, clearly recognized by one skilled in the art.

The response points to pages 1 and 2 of the originally filed specification, which defines the invention as relating to a method for screening compounds for activity in treating an osteoclast related bone disease, a method for screening a chemical compound for activity in the treatment, prevention or alleviation of an osteoclast related bone disease in a subject, and a drug development method. The response asserts that it is readily apparent that the overall object of the present specification is to provide more effective and selective compounds with fewer side effects for the treatment of patients with an osteoclast related bone disease, such as osteoporosis (page 2, lines 9-11).

These arguments are not found persuasive, because the specification teaches that the method of "drug development" comprises "identification of a compound by the method as described above" (page 3, lines 16-17). The method described in the present specification is directed to the following steps (i) providing a test cell comprising one or more chloride channels

of the ClC family; (ii) subjecting the test cell to the action of the chemical compound; and (iii) measuring the ability of the compound to block the selected chloride channels (page 3, 3rd paragraph). The specification envisions measuring the ability of the compound to block a ClC-7 channel by the method disclosed in example 4 (e.g., page 5, 5th paragraph) or by a multitude of techniques known in the art (e.g., page 7, 4th-7th paragraphs). Example 3 describes patch clamp screening for compounds, and example 4 describes Northern blot for ClC-type channels. While the specification provides support for measuring the ability of a compound to block a ClC-7 channel in a test cell, the specification does not provide support for further measuring the efficacy of the compound in treating osteoporosis, osteolytic cancer invasion or Paget's disease of the bone. The specification does not envision specific method steps that would provide a measure of therapeutic efficacy, such as administration of the compound to a cell culture model or animal model of osteoporosis, osteolytic cancer invasion or Paget's disease of bone. The method steps disclosed in the specification do not result in the measurement of efficacy.

The response asserts that it would be readily apparent to one skilled in the art of drug development and pharmacology that in order to measure the efficacy of any chemical compound, it must be established (1) how effective and selective the compounds block the ClC-7 channel as well as (2) the degree of side effects the administration of the compound causes. The response asserts that the efficacy and selectivity of the compounds are determined as described in Examples 3 and 4 or as mentioned on page 6, lines 21-34 in the specification.

These arguments are not found persuasive, because Example 3 describes patch clamp screening for compounds, and example 4 describes Northern blot for ClC-type channels. While the specification provides support for measuring the ability of a compound to block a ClC-7

channel in a test cell, the specification does not provide support for further measuring the efficacy of the compound in treating osteoporosis, osteolytic cancer invasion or Paget's disease of the bone. The cells used in Example 3 are human embryonic kidney (HEK) 293 cells. Patch clamp experiments with these cells exogenously expressing ClC channels (e.g., Example 2) can be used "for screening a chemical compound for activity in blocking the chloride channel ClC-7" and for "screening compounds so as to select compounds having the ability to block the chloride channel ClC-7 but not having the ability to block a chloride channel selected from the group consisting of chloride channels ClC-1, ClC-2, ClC-4, ClC-5, ClC-Ka and ClC-Kb." Thus, the cells can be used to identify blocking activity and specificity of the compound. However, the cells are not osteoclasts and are not involved in the pathology of osteoporosis, osteolytic cancer invasion, or Paget's disease of the bone. Thus, the method of Example 3 is not "measuring the efficacy...in treating osteoporosis, osteolytic cancer invasion, or Paget's disease of bone." Example 4 demonstrates that ClC-7, and not ClC-3 or ClC-6, is expressed in human osteoclasts. This example provides a link between ClC-7 and osteoclast physiology but does not provide a method for taking a compound previously identified as having the ability to block the ClC-7 chloride channel and using measuring the efficacy of the compound in treating osteoporosis, osteolytic cancer invasion, or Paget's disease of bone.

The response asserts that the degree of side effects caused by a compound must be determined before a compound can be used for the manufacture of a medicament for the treatment of a disease and/or before a compound can be used in the treatment of a disease. Thus, the response asserts that the specification inherently discloses the step in the application as filed.

In the instant case, the question is not whether it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a step of measuring therapeutic efficacy. The question is whether the specification describes the step of measuring therapeutic efficacy to put one in possession of the claimed invention. "It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v. American Airlines, Inc.*, 41 USPQ2d 1961, 1964-65 (Fed. Cir. 1997). The originally filed disclosure does not provide support for the claimed step of measuring therapeutic efficacy.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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